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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/385,834	08/30/1999	JEFFREY L. C. WRIGHT	76891	9704

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EXAMINER

QAZI, SABIHA NAIM

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/385,834

Applicant(s)

WRIGHT, JEFFREY L. C.

Examiner

Sabiha N. Qazi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5-11,34,39 and 40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5-11,34,39 and 40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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The request filed on February 17, 2004 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application is acceptable and a CPA has been established. An action on the CPA follows.

Acknowledgement is made of the response filed on February 17, 2004. Claims 1, 5-11, 34, 39 and 40 are pending. No claim is allowed.

Previous rejections are withdrawn due to the enablement and written description issues. Upon careful review of the specification, Examiner has found that there is no example with phytosterol and EPA, DHA, or SA showing the lowering of cholesterol and triglyceride levels in the blood stream in a subject. Examiner notes that the *only* example on Page 12 of the Specification is about the synthesis of Stigmasterol/Omega-3 Fatty Acid Esters.

The Applicant filed a declaration under 37 CFR 1.131 by the inventor Jeffrey L.C. Wright establishing a date of invention prior to December 15, 1998, the filing date of Higgins III. On lines 1 and 2 of page 12 of the Specification, the Applicant has cited US Patent No. 5892068: Higgins III, issued April 6, 1999 (filed August 25, 1998). If the invention was created before December 15, 1998, then why does the specification cite a reference for US 5892068, which was issued almost four months later? The Applicant is requested to clearly show the proper documentation for the priority of this Application.

The declaration filed on 5/5/03 under 37 CFR 1.131 has been considered but is ineffective to overcome the cited reference. The arguments that Higgins III (US Patent 6,147,236) was filed on 12/15/1998 and issued on 11/14/2000 and the date of the present invention is prior to 12/15/1998 because of a communication of the inventor to the Attorney. It is unclear what invention was under consideration at that time. There is no proof that the

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claimed invention was conceived before 12/15/1998 by seeing the copy of the letter. Probably the conception of invention of Higgins III may be prior to 12/15/1998 as this is the filing date.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1, 5-11, 34, 39 and 40 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims are drawn to a nutritional supplement for lowering cholesterol and triglyceride levels in the blood stream of a subject, said nutritional supplement comprising: a sterol ester of an omega-3 fatty acid, wherein said omega-3 fatty acid is selected from the group consisting of EPA, DHA, and SA.

There is no written description for the claimed invention. The Specification only cites the preferred omega-3 fatty acids selected from the group consisting of SA, EPA, and DHA, in lines 16-18 on page 6, and the example about the synthesis of Stigmasterol/Omega-3 Fatty Acid Esters on Page 12.

Therefore, the claimed invention is considered new matter.

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2. Claims 1, 5-11, 34, 39 and 40 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1) The nature of the invention:

A nutritional supplement for lowering cholesterol and triglyceride levels in the blood stream of a subject by sterol ester of an omega-3 fatty acid selected from the group consisting of DHA, EPA, and SA.

(6) The amount of direction or guidance presented

The Specification does not have any direction or guidance for one of ordinary skill in the art for the claimed invention. A disclosure should contain representative examples, which provide reasonable assurance to one skilled in the art that the compounds fall within the scope of a claim will possess the alleged activity. See *In re Riat et al.* (CCPA 1964) 327 F2d 685, 140 USPQ 471; *In re Barr et al.* (CCPA 1971) 444 F 2d 349, 151 USPQ 724.

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See *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) (contrasting mechanical and electrical elements with chemical reactions and physiological activity).

See also *In re Wright*, 999 F.2d 1557, 27 USPQ2d 1510 (Fed. Cir. 1993); *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991), this is because it is not obvious from the disclosure of one species, what other species will work.

(7) the presence or absence of working examples

There are no examples or any data to support the presently claimed invention. The only example is about the synthesis of Stigmasterol/Omega-3 Fatty Acid Esters.

(8) the quantity of experimentation necessary

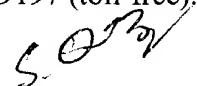
Since there is no data or guidance provided in the Specification, one skilled in the art would have to go through undue experimentation to make and use the claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha N. Qazi whose telephone number is (571) 272-0622. The examiner can normally be reached on any business day.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sabiha N. Qazi, Ph.D.
Primary Examiner
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June 25, 2004